

Applicant : Peters
Appl. No. : 10/595,590
Examiner : Roland Dinga
Docket No. : 13634.4008

REMARKS

The outstanding office action in this application has been carefully considered. Applicant has amended claim 20 to remove the informality noted in paragraph 1 of the office action.

With regard to the rejections on prior art, an overall observation appears appropriate. That observation is that all of the claims as originally presented recited that the heart assist device is “directly” attached to the exterior of an arterial vessel. To make it even more clear that this attachment is to the exterior of an intact blood vessel, the claims have been amended to recite that the heart assist device is directly attached to “an unresected portion” of a blood vessel, i.e., to the exterior wall of an intact blood vessel. The advantage of such external attachment rather than the use of a method or device in which the blood vessel is resected in order to implant the heart assist device are explained, for example, in paragraph 28 of the present application.

Another overall observation is that none of the references relied upon by the Examiner disclose a heart assist device directly attached to a blood vessel. Rather, all of them disclose a device in which a balloon is held in place by a cuff or sleeve such that removal of the cuff or sleeve would result in the heart assist device falling away from the blood vessel. This is not true of the present device in which there is attachment directly to the exterior of a blood vessel.

Claim 1 has been rejected as unpatentable over Buaayu (J.P. 10-328297). However, as can plainly be seen from the abstract and associated drawing of Buaayu, the heart assist device of Buaayu comprises, in pertinent part, a balloon 10 and a “holder” 14 which is in the form of a cuff. If the cuff were removed, the balloon would fall away from the artery 52. Thus, it is respectfully submitted that Buaayu cannot be considered to anticipate claim 1.

Claims 1-6, 12 and 15-17 have been rejected as anticipated by Peters et al. WO 02/24255. Once again, this Peters published application discloses an inflatable cuff which is designed to be

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removable e.g., by loosening sutures 20 or by removing rod 40 which holds segments 36 in place, by detaching strap 78 or by other means described in the Peters et al. publication. Indeed, the very essence of the device of Peters et al. is the “means for releasing the compressing means from about the aorta” which is recited in the claims of that application. This is diametrically opposite to the present invention which is to be directly attached to the exterior wall of the blood vessel. Thus, it is respectfully submitted that Peters et al. cannot be considered to anticipate the claims rejected over it.

Claim 22 has been rejected as anticipated by Peters et al. WO 00/76288. It is respectfully submitted that the portion of the specification of this reference, page 8, lines 30-33, is believed to be directed to the embodiment illustrated in Figures 1A and 1B which are not directed to the use of a balloon, but rather to the use of compression plates indicated by the numeral 4. In this embodiment, it is disclosed at page 11, lines 10-12, that the plates have a plurality of holes 6 that provide means for suturing the plates to the aorta 15 and permitting ingrowth of tissue therethrough. This is consistent with page 8, line 32 which refers to suturing as an alternative to gluing when the compression plates are used.

In the embodiments of this Peters et al. reference in which a balloon is used, e.g., those illustrated in Figures 9a – 10, the balloon is not attached to the blood vessel, but rather is held in place by sheath 65 as described at page 12, lines 22-25. In this balloon embodiment, there is no direct attachment of the balloon to the blood vessel and, in fact, there is no direct attachment of the balloon to the blood vessel at all. Thus, it is respectfully submitted that claim 22 is not anticipated by the Peters et al. reference upon which it has been rejected.

Claims 7-10, 13-14 and 18-21 have been rejected as being unpatentable by reason of obviousness over Peters et al. WO 02/24255. This rejection expressly makes reference to the anticipation rejection based on this reference with regard to claims 1 or 16. However, as discussed

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above, this Peters et al. reference contains no disclosure of direct attachment of a balloon to the exterior wall of a blood vessel. Thus, for this reason alone, it is believed that claims 7-10, 13-14 and 18-21 are patentable over this reference.

In addition, each of the rejections made with regard to claim 7-10, 13-14 and 18-21 are not based on any additional reference and appear to be simply the Examiner's personal view of what would be obvious. It is respectfully submitted that such rejections are improper because they lack any basis for the Examiner's view with regard to obviousness. If the Examiner has any knowledge of a reference which supports his personal view with regard to obviousness, he must either identify that basis or provide an affidavit setting forth the basis for his personal views. Thus, it is respectfully submitted that the rejection based on obviousness is in error and should be withdrawn.

Claims 23-30 are submitted herewith. It is respectfully submitted that these claims are patentable for the reasons set forth with regard to claims 1-22. In addition, it is noted that these claims are presented based on claims that were granted with respect to the corresponding UK patent application.

It is believed that this application is in condition for allowance and a favorable action is respectfully solicited.

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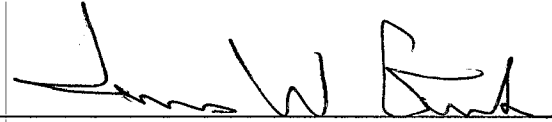
The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,

ORRICK, HERRINGTON & SUTCLIFFE LLP

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By: _____



James W. Geriak, Reg. No. 20,233

Orrick, Herrington & Sutcliffe LLP
4 Park Plaza, Suite 1600
Irvine, CA 92614-2558
Tel. 949-567-6700
Fax: 949-567-6710